# EPA Jacket 54382-3 Vol.3

\*Product ingredient source information may be entitled to confidential treatment\*  $_{Page\ 1\ of\ 3}$ 



Tacktic (EPA Reg. No. 54382-3) convert to unregistered TGAI source Jim Barron

to:

Autumn Metzger 05/16/2012 11:54 AM

Cc:

John Hebert, "Sheehy, Patricia"

Hide Details

From: Jim Barron <jbarron@exponent.com>

To: Autumn Metzger/DC/USEPA/US@EPA

Cc: John Hebert/DC/USEPA/US@EPA, "Sheehy, Patricia" <patricia.sheehy@merck.com>

podate about data for un-rigistered source.

History: This message has been replied to.

1 Attachment



image002.jpg

Dear Autumn,

As a follow up to our recent teleconference, I am writing to you on behalf of Trish Sheehy of Intervet.

As you know, Intervet/Merck is in the process of supporting the use of amitraz TGAI made by the second of the use of amitraz TGAI made by the second of the use of amitraz TGAI made by the second of the use of amitraz TGAI made by the use of amitraz TGAI

Trish has retained Exponent to prepare the registration amendment for Taktik insecticide which will allow the use of the unregistered TGAI source to formulate this end use product. Intervet/Merck does not at this time plan to register an Amitraz Technical (TGAI) product in the US and wishes to continue to source amitraz TGAI from

Below is found the schedule provided by Trish for the remaining studies required to submit the Tactik registration amendment supporting the TGAI source.

Most of the base product chemistry reports are expected by Trish June 30, 2012. Once those reports, especially the 5-batch report, and other production data are made available by the Series A (Product Identity and Composition) report can be written, and the amendment assembled and prepared for submission.

Assuming there are no unanticipated delays in obtaining required information, a realistic timeframe for the complete amendment to be submitted to EPA is August 15, 2012.

#### SUMMARY OF AMITRAZ (Product Chemistry) STUDIES TO BE SUBMITTED TO EPA

OPPTS Guideline Number	EPA Required Data	Pata Report Date Comments		
830-1550	Product identity and composition		Narrative provide by Exponent	
830-1600	Description of materials used		Narrative provide by Exponent	
830-1620	Description of production process		Narrative provide by Exponent	
830-1650	Description of formulation process		Narrative provide by Exponent	
830-1670	Description of formation of impurities		Narrative provide by Exponent	
830-1700	Preliminary (5 batch analysis)	30Jun2012	Report for EUP has been completed to be submitted with ai product chemistry as supplemental information	
830-1750	Certified limits		From batch analysis; reported in CSF	
830-1800	Enforcement Analytical Method	30Jun2012	Active ingredient only	
830-6302	Color	30Jun2012		
830-6303	Physical State	30Jun2012		
830-6304	Odor	30Jun2012		
830-7200	Melting Point	30Jun2012		
830-7300	Density, bulk density, or specific gravity	30Jun2012		
830-7840	Solubility	30Jun2012		
830-7950	Vapor Pressure	30Jun2012		
830-7370	Dissociation Constant	30Jun2012		
830-7550	Octanol/water partition coefficient	3 <b>0</b> Jun2012		
830-7000	Нg	30Jun2012		
830-6313	Stability	30Jun2012		
830-6317	Storage Stability	June, 2013	I-year stability combined with corrosion characteristics	
830-6320	Corrosion characteristics	June, 2013	Combined with 830-6320	

Please let us know if you have any questions.

Jim Barron, Ph. D.

Managing Regulatory Consultant

 $E^{x}$ ponent<sup>®</sup>, Inc. 1000 Centre Green Way Suite 200

Cary, NC 27513

Office Telephone (919) 228-6479 Mobile Telephone (919) 534-6018 Facsimile (919) 228-6501

Email Address jbarron@exponent.com

CONFIDENTIALITY NOTICE: This electronic transmission (including any files attached hereto) may contain information that is privileged, confidential and protected from disclosure. The information is intended only for the use of the individual or entity named above and is subject to any confidentiality Patricia (Trish) A. Sheehy, MS Manager Regulatory Affairs Intervet Inc (d/b/a Merck Animal Health) 556 Morris Avenue, S5-2145A Summit, NJ 07901 USA T 908-473-3551 F 908-473-5560 merck-animal-health.com

December 2, 2011

Document Processing Desk (COADR)
Office of Pesticide Programs (7504C)
U.S. Environmental Protection Agency
Ariel Rios Building
1200 Pennsylvania Avenue, N.W.
Washington, D.C. 20460

RE:

Intervet Inc (d/b/a Merck Animal Health) Letter of Authorization

Intervet Inc (d/b/a Merck Animal Health) has an agreement with EXPONENT, INC. to provide regulatory assistance regarding amitraz TGAI reregistration support. With this letter we confirm EXPONENT INC. as an authorized agent in all matters concerning the regulatory support activities of amitraz technical with the Agency. This letter constitutes authorization for the Office of Pesticide Programs to discuss the status of amitraz technical and supporting data with representatives of EXPONENT INC., including disclosure of trade secret information, and acknowledges that official correspondence from the Office of Pesticide Programs can be directed to the agent. The full name and mailing address of the agent is as follows:

James Barron, Ph.D Managing Regulatory Consultant EXPONENT, INC. 1800 Diagonal Road Alexandria, VA 22314 Tel. (919) 228-6479 e-mail: jbarron@exponent.com

If there are any questions or comments please contact me at 908-473-3551 or patricia.sheehy@merck.com.

Sincerely,

Patricia (Trish) A. Sheehy // Manager, Regulatory Affairs



Re: EPA Reg No 54382-3, Amitraz supply source for TAKTIC, Product

Chemistry and 5-batch analysis Autumn Metzger to: Sheehy, Patricia
Cc: John Hebert, Meredith Laws, James Parker

12/07/20 t1 10:07 AM

12/02/20t1 02:23:28 PM

From: Autumn Metzger/DC/USEPA/US

To: "Sheehy, Patricia" <patricia.sheehy@merck.com>

Cc: John Hebert/DC/USEPA/US@EPA, Meredith Laws/DC/USEPA/US@EPA, James

Parker/DC/USEPA/US@EPA

#### Trish,

The product chemistry guidelines are very straight forward and must be followed for the new source to be accepted. If you have any questions on our guidelines Exponent should be able to help you. Considering that this was brought to your attention exactly a year ago by Julie Chao (in December 2010 via email) and that I followed up numerous times with you in the spring/summer, I do not understand why this has not been completed already and that another full year is being proposed.

The deadline to have this product chemistry submitted is April 2012. If the Agency does not have a revised CSF with any required product chemistry data associated with it (as already explained in previous emails) by April, we will turn the case over to enforcement. If your company sells/manufactures or distributes any product before a revised CSF is accepted you will be violating FIFRA and subject to enforcement action.

In addition, I have yet to receive an authorization letter from your company appointing Jim Barron of Exponent as your consultant and cannot talk further with him until I do.

Autumn Metzger Biologist U.S. Environmental Protection Agency Insecticide-Rodenticide Branch Registration Division (7505P) 1200 Pennsylvania Ave. NW Washington, DC 20460

Tel: 703 305-5314 Fax: 703 308-5433

"Sheehy, Patricia"

Email: metzger.autumn@epa.gov

•

From: "Sheehy, Patricia" <patricia.sheehy@merck.com>
To: Autumn Metzger/DC/USEPA/US@EPA

Autumn

Date: 12/02/2011 02:23 PM

Subject: EPA Reg No 54382-3, Amitraz supply source for TAKTIC, Product Chemistry and 5-batch analysis

Autumn

Time moves quicker than we anticipate but I have been working with the team here regarding our TAKTIC end-use registration and identifying the data needed to ensure that the Agency has the technical information on the ai made at product Chemistry and 5-batch analysis on the technical (the 5-batch analysis on the end-use product is complete). As mentioned to you back in April we stopped production/distribution of our TAKTIC in the US. There is no product in our warehouse or in distribution and we will not initiate any new production until we have completed the work identified above, submitted

under PRIA and EPA has reviewed the data. The 5-batch analysis on the end-use product will be submitted with the rest of the data as one package.

I understand Jim Barron from Exponent has been in contact with you. We have an agreement in place to work with Jim to assist us in this effort. I will send you separately a letter that authorizes him to speak to you on our behalf. Virbac is also an interested party but we, Intervet, are committed to doing the required studies.

That being said we have worked out a draft proposal/plan as per the attached. This proposed plan assumes that the Agency allow us to use the method in the 2010 British Pharmacopia and that we will not be required to do any further validation work. If this is acceptable and we get the work started immediately expediting the 5-batch analysis on the technical we are targeting an April, 2012 submission. Otherwise additional method validation work would push the completion the this study to the end of 3Q/4Q12.

Please advise if this proposal would be acceptable. We have 2 labs lined up and would like to ensure that the work can get started ASAP if possible. I will be in the office until Dec 19th. Intervet will be closed between Dec 23rd and January 2nd for company shut down and holidays. Looking forward to hearing back from you at your earliest convenience.

With kind regards/Mit freundlichen Grüßen/Cordialement

#### Trish

Patricia (Trish) A. Sheehy, M.S.

Regulatory Affairs

T: (908) 473-3551 F: (908) 473-5560

e-mail: patricia.sheehy@merck.com

Notice: This e-mail message, together with any attachments, contains

information of Merck & Co., Inc. (One Merck Drive, Whitehouse Station,

New Jersey, USA 08889), and/or its affiliates Direct contact information

for affiliates is available at

http://www.merck.com/contact/contacts.html) that may be confidential,

proprietary copyrighted and/or legally privileged. It is intended solely

for the use of the individual or entity named on this message. If you are

not the intended recipient, and have received this message in error,

please notify us immediately by reply e-mail and then delete it from



your system. Draft Work Plan for TGAI 12-1-2011.docx



RE: tacktic supply

Sheehy, Patricia to: Autumn Metzger

10/05/2011 12:23 PM

From:

"Sheehy, Patricia" <patricia.sheehy@merck.com>

To:

Autumn Metzger/DC/USEPA/US@EPA

Thank you. That is confirms what I told the team but it helps to have it directly from you. No shipments will take place until we have confirmed our plans and worked through the issues with you.

With kind regards/Mit freundlichen Grüßen/Cordialement Trish

Patricia (Trish) A. Sheehy, M.S.

Regulatory Affairs

T: (908) 473-3551 F: (908) 473-5560

e-mail: patricia.sheehy@merck.com

----Original Message----

From: Metzger.Autumn@epamail.epa.gov [mailto:Metzger.Autumn@epamail.epa.gov]

Sent: Wednesday, October 05, 2011 10:33 AM

To: Sheehy, Patricia

Subject: RE: tacktic supply

The CSF you sent 4/14/11 was not accepted. If that is the current source of what is in supply you are not in compliance and cannot ship.

Autumn Metzger Biologist U.S. Environmental Protection Agency Insecticide-Rodenticide Branch Registration Division (7505P) 1200 Pennsylvania Ave. NW Washington, DC 20460

Tel: 703 305-5314 Fax: 703 308-5433

Email: metzger.autumn@epa.gov

From: "Sheehy, Patricia" <patricia.sheehy@merck.com>

To: Autumn Metzger/DC/USEPA/US@EPA

Date: 10/05/2011 10:15 AM
Subject: RE: tacktic supply

#### Thanks Autumn

We have the source identified in the CSF (sent to you 4/14/2011) and updated version was also provided to the states. The shipping documents are also updated.

I have spoken to Exponent - John Barron. I am finalizing our agreement to

work with Virbac through Exponent With our upper management this week. After which I would talk to you about meeting with John about moving forward with our proposed plan.

With kind regards/Mit freundlichen Grüßen/Cordialement Trish Patricia (Trish) A. Sheehy, M.S.

Regulatory Affairs

T: (908) 473-3551

F: (908) 473-5560

e-mail: patricia.sheehy@merck.com

----Original Message----

From: Metzger.Autumn@epamail.epa.gov [mailto:Metzger.Autumn@epamail.epa.gov]

Sent: Thursday, September 29, 2011 03:57 PM

To: Sheehy, Patricia Subject: tacktic supply

Ηi,

To answer your question about shipping your current product to Puerto Rico, the answer I gathered is:

Your CSF must match the product. So you would have to verify if that source is the one in that product.

Autumn Metzger Biologist U.S. Environmental Protection Agency Insecticide-Rodenticide Branch Registration Division (7505P) 1200 Pennsylvania Ave. NW Washington, DC 20460

Tel: 703 305-5314 Fax: 703 308-5433

Email: metzger.autumn@epa.gov

Notice: This e-mail message, together with any attachments, contains information of Merck & Co., Inc. (One Merck Drive, Whitehouse Station, New Jersey, USA 08889), and/or its affiliates Direct contact information for affiliates is available at

http://www.merck.com/contact/contacts.html) that may be confidential, proprietary copyrighted and/or legally privileged. It is intended solely for the use of the individual or entity named on this message. If you are not the intended recipient, and have received this message in error, please notify us immediately by reply e-mail and then delete it from your system.

Notice: This e-mail message, together with any attachments, contains information of Merck & Co., Inc. (One Merck Drive, Whitehouse Station, New Jersey, USA 08889), and/or its affiliates Direct contact information for affiliates is available at http://www.merck.com/contact/contacts.html) that may be confidential, proprietary copyrighted and/or legally privileged. It is intended solely



### RE: UPDATE TAKTIC 5-Batch Analysis Update Sheehy, Patricia to: Autumn Metzger, Julie Chao

08/02/2011 09:19 AM

From:

"Sheehy, Patricia" <patricia.sheehy@merck.com>

To:

Autumn Metzger/DC/USEPA/US@EPA, Julie Chao/DC/USEPA/US@EPA

#### Autumn

You are correct I have to go back to our site in the EU and find out. They may have run the 5-Batch analysis on the EUP and ai and just sent the final formulation preliminary report.

With kind regards/Mit freundlichen Grüßen/Cordialement Trish

Patricia (Trish) A. Sheehy, M.S.

Regulatory Affairs

T: (908) 473-3551 F: (908) 473-5560

e-mail:

patricia.sheehy@merck.com

----Original Message----

From: Autumn Metzger [mailto:Metzger.Autumn@epamail.epa.gov]

Sent: Wednesday, July 27, 2011 11:19 AM

To: Julie Chao

Cc: Sheehy, Patricia

Subject: Re: UPDATE TAKTIC 5-Batch Analysis Update

Hi Trish,

I am looking at the numbers and I see a lot of 12%...Just to verify, this 5-batch analysis (as part of the entire product chemistry) is supposed to be on the un-registered technical source. Am I reading those numbers right?

Autumn Metzger Biologist U.S. Environmental Protection Agency Insecticide-Rodenticide Branch Registration Division (7505P) 1200 Pennsylvania Ave. NW Washington, DC 20460

Tel: 703 305-5314 Fax: 703 308-5433

Email: metzger.autumn@epa.gov

From: Julie Chao/DC/USEPA/US

To: "Sheehy, Patricia" <patricia.sheehy@merck.com>

Cc: Autumn Metzger/DC/USEPA/US@EPA

Date: 07/27/2011 10:51 AM

Subject: Re: UPDATE TAKTIC 5-Batch Analysis Update

Great...thanks for the update, Trish. I do recall this issue. Either Autumn or I will handle the submission.

Thanks! Julie

From: "Sheehy, Patricia" <patricia.sheehy@merck.com>

To: Julie Chao/DC/USEPA/US@EPA

Date: 07/27/2011 10:48 AM

Subject: UPDATE TAKTIC 5-Batch Analysis Update

Julie:

Just to keep you updated on our progress with the 5-batch analysis of amitraz in the Taktic samples please find below the preliminary results.

Draft report will be available by end of next week.

Right now we are targeting the Week of August 8th for submission.

With kind regards/Mit freundlichen Grüßen/Cordialement Trish Patricia (Trish) A. Sheehy, M.S.

Regulatory Affairs

T: (908) 473-3551 F: (908) 473-5560

e-mail: patricia.sheehy@merck.com

From: Ruan, Sumei

Sent: Tuesday, July 26, 2011 05:40 PM

To: Sheehy, Patricia

Subject: FW: Status of PSL study# 32690 (Taktic Preliminary Analysis)

Hi Trish,

PSL has completed testing the Taktic samples. Below please find the preliminary results. Draft report will be available by end of next week. We should be good on the 8/11 timeline for the final report.

Best regard,

Sumei

From: David Knox [mailto:DavidKnox@productsafetylabs.com]

Sent: Tuesday, July 26, 2011 4:11 PM To: Ruan, Sumei , Sheehy, Patricia

Cc: Carolyn Bowers

Subject: Status of PSL study# 32690 (Taktic Preliminary Analysis)

Hello Sumei,

Please see the attached assay results for the following study.

110701-5H / Lot# 00501B - 12.18% Amitraz 110701-6H / Lot# 00601B - 12.17% Amitraz 110701-7H / Lot# 00804B - 12.38% Amitraz 110701-8H / Lot# 10306B - 12.27% Amitraz 110701-9H / Lot# 10502B - 12.31% Amitraz

I spoke with report writers and you should be receiving a report sometime next week. Please feel free to contact me if you have any additional questions.

Best regards,

David E. Knox III, MS
Study Director
Product Safety Labs (www.ProductSafetyLabs.com)
2394 Highway 130 Suite E
Dayton NJ, 08810
732-438-5100 ext 282
Fax# 732-355-3275
DavidKnox@productsafetylabs.com

The information transmitted is intended only for the person or entity to which it is addressed and may contain confidential and/or privileged material. Any review, retransmission, dissemination or other use of, or taking of any action in reliance upon this information by persons or entities other than the intended recipient is prohibited. If you receive this in error, please contact the sender and delete the material from any computer. Email transmission cannot be quaranteed to be secure or error free as information could be intercepted, corrupted, lost, destroyed, arrive late or incomplete. The sender therefore is in no way liable for any errors or omissions in the content of this message which may arise as a result of email transmission. If verification is required, please request a hard copy. We take reasonable precautions to ensure our emails are free from viruses. You need, however, to verify that this email and any attachments are free of viruses, as we can take no responsibility for any computer viruses, which might be transferred by way of this email. We may monitor all email communication through our networks. If you contact us by email, we may store your name and address to facilitate communication.

information of Merck & Co., Inc. (One Merck Drive, Whitehouse Station, New Jersey, USA 08889), and/or its affiliates Direct contact information for affiliates is available at http://www.merck.com/contact/contacts.html) that may be confidential, proprietary copyrighted and/or legally privileged. It is intended solely for the use of the individual or entity named on this message. If you are not the intended recipient, and have received this message in error, please notify us immediately by reply e-mail and then delete it from your system.

Notice: This e-mail message, together with any attachments, contains information of Merck & Co., Inc. (One Merck Drive, Whitehouse Station, New Jersey, USA 08889), and/or its affiliates Direct contact information for affiliates is available at

Notice: This e-mail message, together with any attachments, contains

http://www.merck.com/contact/contacts.html) that may be confidential, proprietary copyrighted and/or legally privileged. It is intended solely for the use of the individual or entity named on this message. If you are not the intended recipient, and have received this message in error, please notify us immediately by reply e-mail and then delete it from



#### denying amendment for revised CSF for 54382-3

Autumn Metzger o patricia.sheehy

06/29/2011 04:35 PM

Cc: Rosanna Louie-Juzwiak

Hey Trish,

For your submitted CSF amendment, we are able to go ahead and deny your current CSF submission (revising the alternate source) based on lack of data. This said, we are still expecting this being re-submitted through PRIA with the Product chemistry data on the technical source, which includes the 5-batch analysis. Upon review, we may also request the 5-batch on the end-use.

In addition, please submit with that on company letter head the formal letter requested explaining why intervet did not tell the agency about the change in their source.

thanks,

Autumn Metzger Biologist U.S. Environmental Protection Agency Insecticide-Rodenticide Branch Registration Division (7505P) 1200 Pennsylvania Ave. NW Washington, DC 20460

Tel: 703 305-5314 Fax: 703 308-5433

Email: metzger.autumn@epa.gov

Original

#### TRANSMITTAL DOCUMENT

1. NAME AND ADDRESS OF SUBMITTER

Intervet Inc. 556 Morris Avenue, **S**5-2145A Roseland, New Jersey 07068

2. REGULATORY ACTION IN SUPPORT OF WHICH THIS PACKAGE IS SUBMITTED

Notification – CSF - Change in Active Ingredient Source Non-Food, Indoor Use

Product name: TAKTIC Emulsifiable Concentrate Miticide/Insecticide.

EPA File Symbol: 54382-3

3. TRANSMITTAL DATE March 28, 2011

Resent April 8,2011

4. LIST OF SUBMITTED DOCUMENTS (3 copies of each volume)

VOLUME 1

Transmittal document,

1 copy of the cover letter,

1 copy of EPA Application Form 8570-1,

1 copy of EPA Form 8570-34 Certification with Respect to Citation of Data

2 copies the basic CSF's.

5. COMPANY NAME:

Intervet Inc.

556 Morris Avenue, **S**5-2145A Roseland, New Jersey 07068

6. COMPANY OFFICIAL:

Patricia A. Sheehy

Manager, Regulatory Affairs

7. SIGNATURE

000

8. PHONE

908-473-3551



Intervet Inc 556 Morris Avenue, S5-2145A Summit, NJ 07091 Phone: 908-473-3551 Fax: 908-474-5560 www.merck.com Regulatory Affairs

Patricia A. Sheehy, M.S. Manager, Regulatory Affairs

March 28, 2011

Document Processing Desk (NOTIF)
Office of Pesticide Programs (7504P)
U.S. Environmental Protection Agency
Room S-4900, One Potomac Yard
Arlington, VA 22202-4501

Attention: John Hebert (PM #7)

RE: Notification of Change in Source of Supply of Active Ingredient

Intervet Inc, 556 Morris Avenue, Summit, NJ 07901 is submitting the enclosed notification pursuant to PR Notice 98-10 changing the supply for the active ingredient amitraz in the EPA registered product listed below:

TAKTIC Emulsifiable Concentrate Miticide/Insecticide, EPA Reg. No. 54382-3

As per the January 19, 2011 e-mail from Julie Chao Intervet Inc can revise our CSF to list as an unregistered source. We are using the cite all option for required data. EPA Form # 8570-34 "Certification with Respect to Citation of Data" is enclosed identifying our use of the cite-all support and general offer to pay.

"This notification is consistent with the provisions of PR Notice 98-10 and EPA regulations at 40 CFR 152.46, and no other changes have been made to the labeling or the confidential statement of formula of this product. I understand that it is a violation of 18 U.S.C. Sec. 1001 to willfully make any false statement to EPA. I further understand that if this notification is not consistent with the terms of PR Notice 98-10 and 40 CFR 152.46, this product may be in violation of FIFRA and I may be subject to enforcement action and penalties under sections 12 and 14 of FIFRA."

Please find enclosed in triplicate: a transmittal document, one copy of the cover letter, one copy of EPA Application Form 8570-1, one copy of EPA Form 8570-34 Certification with Respect to Citation of Data and two copies the basic CSF's.

If you have any questions regarding this submission, please contact me by telephone at 908-473-3551 or via e-mail at patricia.sheehy@sp.intervet.com.

Sincerely,

Patricia A. Sheehy, M.S.

Manager, Regulatory Affairs

Please read instructions on reverse before completing form.	Form Appre	ved. OMB No. 2070-0060	Print Form		
United States  Environmental Protection  Washington, DC 20	7 '	Registration  X Amendment Other	OPP Identifier Number		
Application	on for Pesticide - Sect	ion I			
1. Compeny/Product Number 54382-3	2. EPA Product Mana John Herbert	·	3. Proposed Classification		
4. Compeny/Product (Name) Intervet inc	<b>PM#</b> 07		None Restricted		
5. Name and Address of Applicant (Include ZIP Code)  556 Morris Avenue, S5-2145A  Summit NJ 0790 t	6. Expedited Review. In accordance with FIFRA Section 3(c)(3) (b)(i), my product is similar or identical in composition and labeling to:  EPA Reg. No.				
Check if this is a new address	Product Name				
	Section - II				
Amendment - Expisin below.  Resubmission in response to Agency letter deted  Notification - Expisin below.	Final printed Agency iette "Me Too" Ap  Other - Expis	pplication.	All plants to a second		
Explanation: Use odditional pagetal if necessary. (For section I end Section II.)  Revised CSF listing as unregistered source of active ingredient used in end-use product. As per 1-19-2011 communication with EPA this submission does not need to be submitted under PRIA category R340. Cite all method of data citation is being used to support this application					
	Section - III				
1. Material This Product Will Be Packaged In:					
Child-Resistant Peckaging  Yes*  No  * Certification must  If "Yes"  Unit Packaging  No. per Unit Packaging wgt. conteiner	Weter Soluble Peckaging Yes No If "Yes" No. per Package wgt centainar	2. Type of Contains:  Metal Plastic Glass Peper Other (S)	pacify!		
be submitted					
3, Location of Net Centents Information 4. Size(s) Re Lebel Container	tail Container	5. Location of Label Directier On Label On Labeling accemy			
6. Manner in Which Label is Affixed to Product Lithog Paper Stend	aph Other				
	Section - IV				
1. Contact Point (Complete items directly below for identification)	n of individual to be contacted, h	f necessary, to process this	application.)		
Name Patricia A. Sheehy, M.S.	Title Manager, Reg. Affairs		elephone No. (include Ares Code)		
Certification  I certify that the statements I have made on this form and all attachments therete are true, accurate and complete.  I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law.			Received		
2. Signature	3. Title  Manager, Regulatory Affairs				
4. Typed Nams Patricia A. Sheehy, M.S.	5. Dere Mar <b>1%</b> , 201 l				

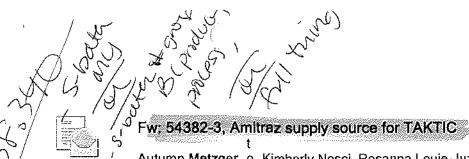


## UNITED STATES ENVIRONMENTAL PROTECTION AGENCY 1200 Pennsylvania Avenue, N.W. WASHINGTON, D.C. 20460

rting burden for this collection of information is estimated to as a 2 25 hour for registration

and 0.25 hours per response for reregistration and special review activities, including time for comments regarding burden estimate or any other aspect of this collection of information, incl. Strategies Division (2822T), U.S. Environmental Protection Agency, 1200 Pennsylvania Averto this address.	reading the instruction uding suggestions for i	s and completing the necessary forms. Send reducing the burden to: Director, Collection		
Certification with Respect to Citation of Data				
Applicant's/Registrant's Name, Address, and Telephone Number Intervet tnc. 556 Morris Avenue, S5-2f42A, Summit NJ 07901 908-473-3551		EPA Registration Number/File Symbol 54382-3		
Active Ingredient(s) and/or representative test compound(s) INDOXACARB / PERMETHRIN		Date March 28, 2011		
General Use Pattem(s) (list all those claimed for this product using 40 CFR Part t58 INDOOR	Product Name TAKTIC Emulsifiable Conc			
NOTE: If your product is a 100% repackaging of another purchased EPA-registered product labeled for all the same uses on your label, you do not need to submit this form. You must submit the Formulator's Exemption Statement (EPA Form 8570-27).				
t am responding to a Data-Call-tn Notice, and have included with this form a be used for this purpose).	list of companies se	nt offers of compensation (the Data Matrix form should		
SECTION I: METHOD OF DATA SUPPORT (Check one method only)				
I am using the cite-all method of support, and have included with this form a list of companies sent offers of compensation (the Data Matrix form should be used for this purpose).  I am using the selective method of support (or cite-a under the selective method), and have included with completed list of data requirements (the Data Matrix used).				
SECTION (I: GENERAL	OFFER TO PAY			
[Required if using the cite-all method or when using the cite-all option under the selection of the cite-all options of				
	<del>.</del>			
SECTION (II): CERT	FICATION			
I certify that this application for registration, this form for reregistration, or the application for registration, the form for reregistration, or the Data-Call-In response. In indicated in Section I, this application is supported by all data in the Agency's files that substantially similar product, or one or more of the ingredients in this product; and (2) requirements in effect on the date of approval of this application if the application souguses.	n addition, if the cite-of t (1) concern the pro- is a type of data that	all option or cite-all option under the selective method is perties or effects of this product or an identical or would be required to be submitted under the data		
I certify that for each exclusive use study cited in support of this registration the written permission of the original data submitter to cite that study.	or reregistration, tha	at I am the original data submitter or that I have obtained		
I certify that for each study cited in support of this registration or reregistrati submitter; (b) I have obtained the permission of the original data submitter to use the compensation have expired for the study; (d) the study is in the public literature; or (e) offered (I) to pay compensation to the extent required by sections 3(c)(1)(F) and/or 3(d) amount and terms of compensation, if any, to be paid for the use of the study.	study in support of the thave notified in wri	nis application; (c) all periods of eligibility for ting the company that submitted the study and have		
I certify that in all instances where an offer of compensation is required, cop- accordance with sections 3(c)(t)(F) and/or 3(c)(2)(B) of FIFRA are available and will I evidence to the Agency upon request, I understand that the Agency may initiate action	be submitted to the A	gency upon requect. Should I fail to produce such suspend the registration of my product in conformity with		
FIFRA.		Control of the contro		
t certify that the statements i have made on this form and all attachments to it are true, accurate, and complete. I acknowledge that any knowingly false or misteading statement may be punishable by fine or imprisonment or both under applicable taw.				
Signatura	Date	Typed or Printed Name and Title		
Signature	March 28, 2011	Patricia A. Sheehy, Manager Regulatory Affairs		

EPA Form 8570-34 (12-2003) Electronic and Paper versions available. Submit only Paper version.



Autumn Metzger o Kimberly Nesci, Rosanna Louie-Juzwiak

05/26/20 t t 02: t6 PM

Is Intervet's time line acceptable? should we clarify that they cannot make any product? I have no clue about the specifics of the objective of the 5-batch. Should I just refer her to the guidelines to not get us into any trouble confirming anything that may not be 100% accurate?

Autumn Metzger Biologist U.S. Environmental Protection Agency Insecticide-Rodenticide Branch Registration Division (7505P) 1200 Pennsylvania Ave. NW Washington, DC 20460

Tel: 703 305-5314 Fax: 703 308-5433

Email: metzger.autumn@epa.gov

---- Forwarded by Autumn Metzger/DC/USEPA/US on 05/26/2011 02:14 PM -----

From:

"Sheehy, Patricia" <patricia.sheehy@sp.intervet.com>

To: Date:

Autumn Metzger/DC/USEPA/US@EPA 05/26/20 t1 0 t:57 PM

Subject:

RE: 54382-3, Amitraz supply source for TAKTIC

#### Autumn:

My apologies - the Head of our Chain Supply EU team is on vacation and I had to urgently pull in others to discuss the amitraz 5-batch analysis study requirement.

As of now we have determined that we have the reference standards and batches available for testing. This would not be done in-house but rather (due to urgent timing) at PSL, an outside contract laboratory. Currently we have a 5-batch analysis study for another product scheduled to start at PSL within the next 3-4 weeks. Our Chain Supply team is going to talk to them about substituting the amitraz study and moving the schedule up (if possible].

Based on our team discussion this afternoon we are working toward starting the study in June. Since this is a 3-month study the final report would be submitted to you in September with the Certificates of Analysis referred to in my previous e-mail May 19, 2011.

Just to confirm, the objective of the 5-batch analysis is to determine the percentage of amitraz active ingredient in the test substance (TAKTIC). The strength or percent by weight of the active ingredient of the test substance will be determined by comparing chromatographic responses with those of reference materials of known purities. The identity of the active ingredient in the test substance will be confirmed by comparing the retention time of the reference material with that of the corresponding chromatographic responses in solution of the test substance.

Once we have confirmed timing of the study I can provide progress reports to

you on a bi-weekly or monthly basis until the study is completed.

Please advise if this is acceptable to meet EPA's request and still maintain product for customers.

With kind regards/Mit freundlichen Grüßen/Cordialement

Patricia (Trish) A. Sheehy, M.S.

Regulatory Affairs

T: (908) 473-3551 F: (908) 473-5560

e-mail: patricia.sheehy@sp.intervet.com

----Original Message----From: Sheehy, Patricia

Sent: Tuesday, May 24, 2011 03:36 PM To: 'Metzger.Autumn@epamail.epa.gov'

Subject: RE: 54382-3, Amitraz supply source for TAKTIC

#### Autumn:

I'll contact our European office and Baton Rouge facility to determine when this can be completed and get back to you tomorrow.

Thanks for the response.

With kind regards/Mit freundlichen Grüßen/Cordialement Trish Patricia (Trish) A. Sheehy, M.S.

Regulatory Affairs

T: (908) 473-3551 F: (908) 473-5560

e-mail: patricia.sheehy@sp.intervet.com

----Original Message----

From: Metzger.Autumn@epamail.epa.gov (mailto:Metzger.Autumn@epamail.epa.gov) Sent: Tuesday, May 24, 2011 02:26 PM

To: Sheehy, Patricia

Subject: RE: 54382-3, Amitraz supply source for TAKTIC

Hey Trish,

We really will need the 5-batch analysis done by our standards. You are welcome to send this in addition, however send them all together so the product chemistry department will have everything at the same time. I don't know off the type of my head the PRIA category, you'll have to see the options. formula change with RD review....

What is the earliest you can begin this testing? This should be a rather quick test to perform.

Autumn Metzger Biologist U.S. Environmental Protection Agency Insecticide-Rodenticide Branch Registration Division (7505P) 1200 Pennsylvania Ave. NW

Washington, DC 20460

Tel: 703 305-5314 Fax: 703 308-5433

Email: metzger.autumn@epa.gov

From: "Sheehy, Patricia" <patricia.sheehy@sp.intervet.com>

To: Autumn Metzger/DC/USEPA/US@EPA

Cc: Rosanna Louie-Juzwiak/DC/USEPA/US@EPA, Kimberly

Nesci/DC/USEPA/US@EPA

Date: 05/24/2011 09:03 AM

Subject: RE: 54382-3, Amitraz supply source for TAKTIC

#### Autumn:

Just a follow-up on the amitraz question below regarding the Certificates of Analysis. I was wondering how to handle the submission (if acceptable) and what PRIA category this would fall under.

With kind regards/Mit freundlichen Grüßen/Cordialement Trish Patricia (Trish) A. Sheehy, M.S.

Regulatory Affairs

T: (908) 473-3551 F: (908) 473-5560

e-mail: patricia.sheehy@sp.intervet.com

----Original Message-----From: Sheehy, Patricia

Sent: Thursday, May 19, 2011 01:04 PM To: 'Metzger.Autumn@epamail.epa.gov'

Cc: Louie-Juzwiak.Rosanna@epamail.epa.gov;

Nesci.Kimberly@epamail.epa.gov

Subject: RE: 54382-3, Amitraz supply source for TAKTIC

Importance: High

#### Autumn

I double checked with our European offices. We do not have a current 5 batch analysis study but I do have Certificates of Analysis (CofAs) from March 31, 2005 (3) batches purchased from Bayer CropScience, CofAs from 6 batches purchased from Bayer in October 2005 and CofAs from 7 batches that were shipped from to our Baton Rouge LA facility in 2007 (1) and 2010 (6).

Would this be acceptable for submission now? If so I how would I identify the submission - and what would the correct PRIA code be. R340 is an amendment to the end-use product and I am not sure if this would be correct for this type of submission.

With kind regards/Mit freundlichen Grüßen/Cordialement Trish Patricia (Trish) A. Sheehy, M.S. Regulatory Affairs

T: (908) 473-3551 F: (908) 473-5560 e-mail: patricia.sheehy@sp.intervet.com

----Original Message----

From: Metzger.Autumn@epamail.epa.gov [mailto:Metzger.Autumn@epamail.epa.gov] Sent: Thursday, May 12, 2011 03:24 PM

To: Sheehy, Patricia

Cc: Louie-Juzwiak.Rosanna@epamail.epa.gov;

Nesci.Kimberly@epamail.epa.gov

Subject: 54382-3, Amitraz supply source for TAKTIC

Hello Trish,

As a follow-up to our phone conversation, the application you submitted, per the Ageny's request to update the source of amitraz for 54382-3 is not complete. I understand that the Agency recommended a "cite-all" option to support your data requirements, however it appears that we do not have enough information on record for this option. A 5-batch analysis will need to be submitted to the Agency to ensure that the product you are buying is the same as the one before.

Since this issue is time-sensitive as your product is currently out of FIFRA compliance, please have this 5-batch analysis either conducted immediately or send in the study if you already have it. From our phone conversation today, you believed you had the study in-house and could have it sent in to the Agency by next week. Please remember this submission will now be considered a PRIA action and to be reviewed.

Please contact me directly for questions or to discuss CBI issues should not be put in an email.

Thank you for your continued aid in resolving this issue,

Autumn Metzger Biologist U.Ş. Environmental Protection Agency Insecticide-Rodenticide Branch Registration Division (7505P) 1200 Pennsylvania Ave. NW Washington, DC 20460

Tel: 703 305-5314 Fax: 703 308-5433

Email: metzger.autumn@epa.gov

Notice: This e-mail message, together with any attachments, contains information of Merck & Co., Inc. (One Merck Drive, Whitehouse Station, New Jersey, USA 08889), and/or its affiliates Direct contact information for affiliates is available at

http://www.merck.com/contact/contacts.html) that may be confidential, proprietary copyrighted and/or legally privileged. It is intended solely for the use of the individual or entity named on this message. If you are not the intended recipient, and have received this message in error, please notify us immediately by reply e-mail and then delete it from your system.

Notice: This e-mail message, together with any attachments, contains information of Merck & Co., Inc. (One Merck Drive, Whitehouse Station,

New Jersey, USA 08889), and/or its affiliates Direct contact information for affiliates is available at http://www.merck.com/contact/contacts.html) that may be confidential, proprietary copyrighted and/or legally privileged. It is intended solely for the use of the individual or entity named on this message. If you are not the intended recipient, and have received this message in error, please notify us immediately by reply e-mail and then delete it from your system.



RE: Amitraz

Autumn Metzger to: Sheehy, Patricia

03/10/201 t 08:34 AM

From:

Autumn Metzger/DC/USEPA/US

To:

"Sheehy, Patricia" <patricia.sheehy@sp.intervet.com>

#### Hello Trish,

I have taken over Amitraz since Julie's departure although she still helped out with some issues while here in December (including the one below regarding your CSFs for the source of amitraz). The Agency has not seen any updated CSFs and this is currently a major FIFRA violation. We need to know where you are with this and when we can expect to see this fixed.

Please call me or email me to discuss.

Autumn Metzger Biologist U.S. Environmental Protection Agency Insecticide-Rodenticide Branch Registration Division (7505P) 1200 Pennsylvania Ave. NW Washington, DC 20460

Tel: 703 305-5314 Fax: 703 308-5433

Email: metzger.autumn@epa.gov

"Sheehy, Patricia" Julie: Thank you for the quick follow-up. In an ef... 01/19/2011 04:15:12 PM

From:

"Sheehy, Patricia" <patricia.sheehy@sp.intervet.com>

To:

Julie Chao/DC/USEPA/US@EPA

Cc:

Autumn Metzger/DC/USEPA/US@EPA, John Hebert/DC/USEPA/US@EPA

Date:

01/19/201 t 04:15 PM

Subject:

RE: Amitraz

#### Julie:

Thank you for the quick follow-up. In an effort to have this done quickly I will pass this on to our consultant TSG who has been helping me out with the amitraz and permethrin reregistrations and will use the cite-all option as suggested.

With kind regards/Mit freundlichen Grüßen/Cordialement Patricia (Trish) A. Sheehy, M.S. Regulatory Affairs (908) 473~3551 T:(908) 473~5560 F:patricia.sheehy@sp.intervet.com e-mail: ----Original Message----From: Chao.Julie@epamail.epa.gov [mailto:Chao.Julie@epamail.epa.gov] Sent: Wednesday, January 19, 2011 03:24 PM

To: Sheehy, Patricia

Cc: Metzger.Autumn@epamail.epa.gov; Hebert.John@epamail.epa.gov

Subject: Amitraz

Hi Trish,

John and I spoke about the amitraz situation. You can revise your CSF to list as an unregistered source, but you will need to provide or cite the required data. This does need to be submitted under PRIA category R-340. you cite the data, you have the selective citation and cite-all options. cite-all option greatly simplifies the review process, and would help to expedite processing.

Thanks, Julie

Julie Chao 703.308.8735 (phone) 703.305.6920 (fax)

http://www.epa.gov/pesticides

Notice: This e-mail message, together with any attachments, contains information of Merck & Co., Inc. (One Merck Drive, Whitehouse Station, New Jersey, USA 08889), and/or its affiliates Direct contact information for affiliates is available at http://www.merck.com/contact/contacts.html) that may be confidential, proprietary copyrighted and/or legally privileged. It is intended solely for the use of the individual or entity named on this message. If you are

not the intended recipient, and have received this message in error, please notify us immediately by reply e-mail and then delete it from your system.



Fw: Amitraz: Intervet Using Unregistered Amitraz Source\*\*\*\*

Julie Chao to: Autumn Metzger

12/22/2011 06:50 AM

F	ď	a	r	Y	'n	
4		v	ŀ	4	1	,

Julie Chao/DC/USEPA/US

To:

Autumn Metzger/DC/USEPA/US@EPA

History:

This message has been replied to.

Hi Autumn,

It was James Parker who contacted Intervet in December 2010...they spoke over the phone, but attached is Intervet's 12/20 response. Is this what you were looking for?

Julie

Julie Chao 703.308.8735 (phone) 703.305.6920 (fax)

http://www.epa.gov/pesticides

----- Forwarded by Julie Chao/DC/USEPA/US on 12/22/2011 06:48 AM -----

From:

James Parker/DC/USEPA/US

To:

Julie Chao/DC/USEPA/US@EPA

Cc:

Venus Eagle/DC/USEPA/US@EPA, John Hebert/DC/USEPA/US@EPA

Date:

12/21/2010 09:47 AM

Subject:

Amitraz: Intervet Using Unregistered Amitraz Source\*\*\*\*

Hí all,

In reference to amitraz, I have been in contact with who supplies and Intervet (end-user who supplies ) trying to understand the current status of their labels. In any case the short story is that Intervet cites on their CSF's however, Intervet is actually buying unregistered Amitraz product from which is a Company in who manufactures amitraz). Intervet, has contacted me and informed me that they have stopped production of their product (TACKTIC), however they are currently looking for the Okay from the EPA to move forward. In any case I wanted to notify you per they need to submit a new CSF and not continue using registration since they are not using product.

Please find the email with the background information regarding this issue from Intervet below (with the full explanation attached below).

James P. 703-306-0469

From:

"Sheehy, Patricia" <patricia.sheehy@sp.intervet.com>

To:

James Parker/DC/USEPA/US@EPA

Cc:

"Neil Sheehy" <sheehy4@embarqmail.com>

Date:

12/20/2010 04:01 PM

Subject:

Summary of AMITRAZ AI SUPPLY to INTERVET

Mr. Parker:

As per our discussion attached is information I have summarized which I hope will help you understand our current amitraz ai supply and the previous agreements with

Since I will be out of the office until January 4th my cell phone number is 908-674-1331, if you have any questions related to this information. This product was acquired when INTERVET merged with Schering-Plough in 2007. I hope I can help you with some of the history. I am sure, however, that I can contact someone in the EU if necessary should you have any questions I cannot address.

<<12-20-2010 AMITRAZ Ai STATUS.doc>>

Happy Holidays and the Best of New Years.

With kind regards/Mit freundlichen Grüßen/Cordialement

Trish

Patricia (Trish) A. Sheehy, M.S.

Regulatory Affairs

T: (908) 473-3551 F:

(908) 473-5560

e-mail: patricia.sheehy@sp.intervet.com

This e-mail message, together with any attachments, Notice: contains

information of Merck & Co., Inc. (One Merck Drive, Whitehouse Station,

New Jersey, USA 08889), and/or its affiliates Direct contact information

for affiliates is available at

http://www.merck.com/contact/contacts.html) that may be confidential,

proprietary copyrighted and/or legally privileged. It is intended solely

for the use of the individual or entity named on this message. If

not the intended recipient, and have received this message in

please notify us immediately by reply e-mail and then delete it from

your system.

12-20-2010 AMITRAZ Ai STATUS.doc

## Material to be added to a Mini-Jacket (in the case where an e-Jacket exists)

Reg. No. <u>54382-3</u>
Send to SIG: check box [] This material is:
<ul> <li>€ New csp</li> <li>€ Notification</li> <li>€ Final Printed Label</li> <li>€ Other:</li> </ul>
Instructions: Attach this notice on top of the material. It must be clipped all together and there should be NO STAPLES in the material. Then give the material with this coversheet to staff in the Information Services Center (Room 230).
Reviewer's Name: Y. UB-Di
Phone: 306-0415 Division: RD
Date: 3-19-07



## UNITED STATES ENVIRONMENTAL PROTECTION AGENCY WASHINGTON, D.C. 20460

OFFICE OF PREVENTION, PESTICIDES AND TOXIC SUBSTANCES

Mary Hagler Intervet, Inc. 29160 Intervet Lane Millsboro, DE 19966

MAR 1 9 2007

Dear Ms. Hagler:

Subject:

Revised Basic Confidential Statement of Formula

Taktic Emulsifiable Concentrate Miticide/Insecticide

EPA Registration No. 54382-3

The Agency has reviewed your submission for a revised Confidential Statement of Formula, and the following comment applies:

The Confidential Statement of Formula dated January 12, 2007 for the basic formulation agrees with the label claim in compliance with PR Notice 91-2 and is acceptable.

The Confidential Statement of Formula has been added to your file as part of the record.

Sincerely yours

Káble Bo Davis Entomologist

Insecticide-Rodenticide Branch Registration Division (7505P)

CC: Amaris Johson



10 July 2006

Amaris Johnson
U. S. EPA
Office of Pesticide Programs
Special Review and Reregistration Division
2777 South Crystal Drive
Arlington, VA 22202

RE: CSF for Taktic Emulsifiable Concentrate Miticide/Insecticde EPA Reg. No. 54382-3

Dear Ms. Johnson:

As requested, enclosed is an updated Confidential Statement of Formulation (CSF) for Taktic Emulsifiable Concentrate Miticide/Insectide, EPA Reg. No. 54382-3.

If I can be of any further assistance, please contact me by telephone at 302-934-4340 or by e-mail at <a href="mailto:mary.hagler@intervet.com">mary.hagler@intervet.com</a>.

Best regards,

Mary K. Hagler, MS, MS, RAC

Mary K. Hagen

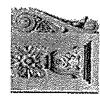
Pharmacovigilance and Product Stewardship Manager Pharmaceuticals

Enclosure

7/12/06

\*Manufacturing process information may be entitled to confidential treatment\*

\*Product ingredient source information may be entitled to confidential treatment\*



John Hebert/DC/USEPA/US 01/10/2007 11:55 AM To martin.tiemann@intervet.com

cc Amaris Johnson/DC/USEPA/US@EPA

pcc

Subject Fw: Taktic CSF

Mr. Tiemann - I was told that Mary Hagler no longer works for intervet. Let me know if you have any questions.

John Hebert

---- Forwarded by John Hebert/DC/USEPA/US on 0 t/10/2007 t0:t8 AM -----



John Hebert/DC/USEPA/US

0t/t0/2007 09:34 AM

To mary.hagler@intervet.com

cc Amaris Johnson/DC/USEPA/US@EPA

Subject Taktic CSF

Ms. Hagler - I'm reviewing your revised basic CSF for Taktic Emulsifiable Concentrate (EPA Reg. No. 54382-3). There is a problem with the nominal concentration of amitraz. The label claim (nominal) is 12.5% amitraz. But according to the CSF the nominal is 12.9% amitraz. Based on my calculations (and based on 100 lbs of final product), you need to add of the source material. Since you will be slightly decreasing the amount of source added by you'll need to make that up in one (or more) of the inerts. Everything else on the CSF looks OK. Once you make the correction you can submit it to me electronically as a pdf file. If you are uncomfortable with that (because I can't guarantee that email is totally secure), you can mail to my attention. Please let me know if you have any questions.

Regards, John Hebert 703-308-6249

